

**IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF OKLAHOMA**

UNITED STATES OF AMERICA
AND STATE OF OKLAHOMA,
ex rel. Clark Ward, M.D.

Plaintiff,

vs.

OKLAHOMA PROCURE MANAGEMENT,
LLC, a Delaware limited liability company;
PROCURE TREATMENT CENTERS, INC., a
Delaware corporation; RADIATION
MEDICINE ASSOCIATES, P.C., a professional
corporation; and PROTON CENTER
DEVELOPMENT CORPORATION, a
California corporation; LOUGHLIN
MANAGEMENT, a New York corporation;
ANDREW KNIZLEY, an individual; HADLEY
FORD, an individual; JAMES LOUGHLIN, an
individual; JOHN TAYLOR, M.D., an
individual; LUCIUS DOH, M.D., and individual;
GARY LARSON, M.D., an individual;
ROBERT GASTON, M.D., an individual;
KIRAN PRABHU, M.D., an individual;
MICHAEL CONFER, M.D., an individual;
MELISA BOERSMA, M.D., an individual;
ELAINE NORDHUES, M.D., an individual;
ANDREW CHANG, M.D., an individual; LES
YONEMOTO, M.D., an individual,

Defendants.

CIV-15-1260-M

FILED UNDER SEAL

**COMPLAINT FOR VIOLATIONS OF FEDERAL FALSE CLAIMS ACT,
ANTI-KICKBACK STATUTE, AND PHYSICIAN SELF-REFERRAL LAWS**

Qui Tam Relator Clark Ward, M.D. ("Relator") brings this action on his own behalf and on behalf of the United States of America and State of Oklahoma to recover civil damages and penalties under the False Claims Act, 31 U.S.C § 3729, *et seq.*, the Oklahoma Medicaid False Claims Act, 63 O.S. § 5053.1, and the Oklahoma Medicaid Program Integrity Act, 56 O.S. §

1005, against Defendants Oklahoma ProCure Management, LLC (“ProCure OKC”), ProCure Treatment Centers, Inc. (“Parent”) (“ProCure OKC” and “Parent” shall be collectively referred to as “ProCure”), Radiation Medicine Associates, P.C. and its shareholders/owners (collectively referred to as “RMA” unless otherwise specified), Proton Center Development Corporation and its members (collectively referred to as “PCDC” unless otherwise specified), Andrew Knizley (“Knizley”), Hadley Ford (“Ford”), James Loughlin (“Loughlin”), John Taylor, M.D. (“Dr. Taylor”); Lucius Doh, M.D. (“Dr. Doh”), Gary Larson, M.D. (“Dr. Larson”), Robert Gaston, M.D. (“Dr. Gaston”), Kiran Prabhu, M.D. (“Dr. Prabhu”), Michael Confer, M.D. (“Dr. Confer”), Melisa Boersma, M.D. (“Dr. Boersma”), Elaine Nordhues, M.D. (“Dr. Nordhues”), Andrew Chang, M.D. (“Dr. Chang”) Les Yonemoto, M.D. (“Dr. Yonemoto”).

I. INTRODUCTION

1. Relator’s allegations relate to medical director agreements and consulting arrangements between ProCure OKC and RMA, and between PCDC and both ProCure OKC and Parent, respectively, all of which violate federal and state law.

2. Defendants ProCure OKC, by and through its agents, employees, or any combination thereof, entered into a Medical Director Agreement with RMA and RMA’s physicians (“RMA Agreement”) for the purpose, in part, of obtaining recommendations and referrals for proton therapy to ProCure’s Oklahoma City proton therapy facility (“OKC Facility”) in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and the Oklahoma Anti-Kickback Statute, 63 O.S. § 1-742.

3. Defendants ProCure, by and through their agents, employees, or any combination thereof, entered into two (2) consulting agreements with PCDC and PCDC’s physicians (“Consulting Agreement”) for the purpose, in part, of obtaining recommendations and referrals

for proton therapy to the OKC Facility in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and the Oklahoma Anti-Kickback Statute, 63 O.S. § 1-742.

4. As will be more specifically plead herein, there was and is a financial relationship between PCDC and ProCure which makes referrals by PCDC to the OKC Facility in violation of the federal physician self-referral law, 42 U.S.C. § 1395nn (commonly referred to as the “Stark Law”).

5. Defendants all violated the Federal False Claims Act, 31 U.S.C. § 3729, *et seq.*, (“FCA”) and the Oklahoma Medicaid False Claims Act (“OMFCA”), 63 O.S. § 5053.1, and the Oklahoma Medicaid Program Integrity Act (“OMPIA”), 56 O.S. § 1005.

6. Knowing that they were ineligible for payments due to violations of the Anti-Kickback and Stark Laws, Defendants submitted false or fraudulent records, statements, or claims, or any combination thereof, for reimbursement to Medicare and Medicaid. All Defendants conspired to defraud the federal and state government by submitting false or fraudulent claims that were paid by Medicare, Medicaid, and other federally funded health programs.

7. By directing payments to RMA and PCDC physicians in violation of federal and state law, ProCure was able to maintain lucrative referrals and maintain a patient base that they otherwise did not and would not have had at the OKC Facility.

II. JURISDICTION AND VENUE

8. This action arises under the Federal False Claims Act, 31 U.S.C. § 3729 *et seq.*, the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and the Stark Law, 42 U.S.C. § 1395nn. Therefore, this Court has jurisdiction pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732(a).

9. This Court has jurisdiction over Plaintiff's claims against Defendants for violations of the Oklahoma Anti-Kickback Statute, OMFCA, and OMPIA (collectively referred to as the "Oklahoma Law Violations"), pursuant to 28 U.S.C. § 1367(a) and 31 U.S.C. § 3732(b) because Defendants' Oklahoma Law Violations and violations of the federal laws arise from the same transactions or occurrences.

10. Venue is proper under 28 U.S.C. § 1391(b) because Defendants transact business within this district and the facts forming the basis of this Complaint occurred within this district.

11. Relator is the original source of the information upon which this Complaint is based. Contemporaneously with this filing, he has provided disclosures of the allegations within this Complaint to the United States Attorney for the Western District of Oklahoma and the Oklahoma Attorney General's office, disclosing substantially all the material evidence and information Relator possesses.

12. The facts and circumstances of Defendants' violations have not been publically disclosed in a criminal, civil, or administrative hearing, nor in any congressional or administrative report, hearing, audit, or in any investigation, or in the media.

III. PARTIES

13. Relator Clark Ward, M.D. is a resident of Oklahoma and a citizen of the United States. Relator was a top executive of ProCure OKC from 2012 until 2015 when he was terminated for refusing to be "docile" about his concerns that federal and state laws were being violated. Relator is a Board-Certified radiologist who earned his medical degree from Tulane University School of Medicine in 1978.

14. The real parties in interest to the claims set forth herein are the United States of America and the State of Oklahoma.

15. Defendant ProCure OKC is the limited liability company that operates the OKC Facility. ProCure OKC's majority owner is ProCure Midwest Holdings, LLC, whose managing member is Oklahoma ProCure Holdings, LLC. ProCure OKC is controlled by the Parent. ProCure OKC's principal place of business is Oklahoma City, Oklahoma.

16. Defendant Parent is the corporation that controls ProCure OKC, the OKC Facility, and other related and/or affiliated entities. Its principal place of business is in Bloomington, Indiana.

17. Defendant RMA is a professional corporation owned, through various investment vehicles, by radiation oncologists. RMA is a party to the RMA Agreement. Some of the physicians who practice within RMA are considered owners or investors or both, and some are employees. All have a financial interest in RMA and/or ProCure OKC. Three physician owners/investors of RMA are or were members of ProCure OKC's Board of Directors.

18. Defendant Loughlin Management is a corporation with James Loughlin as its principal member. Loughlin Management is the management company brought in to make ProCure OKC more profitable, and has a financial interest in ProCure OKC. Its principal place of business is New York City, New York.

19. Defendant Andrew Knizley, on information and belief, is a resident of Tennessee and a citizen of the United States. Knizley is the current COO of Parent. He has a financial interest in ProCure OKC, and exerts significant influence over it.

20. Defendant Hadley Ford, on information and belief, is a resident of New York and a citizen of the United States. Ford was a top executive of Parent who exerted control over ProCure OKC during the execution and implementation of the RMA Agreement.

21. Defendant James Loughlin, on information and belief, is a resident of New York and a citizen of the United States. Loughlin has a financial interest in Loughlin Management and in ProCure OKC.

22. Defendant John Taylor, M.D. is a resident of Oklahoma and a citizen of the United States. Dr. Taylor has a financial interest in RMA and ProCure OKC. He is a part owner of RMA and also a member of Radiation Medicine Investments, LLC, an Oklahoma limited liability company ("RMI"), a member of Procure OKC.

23. Defendant Lucius Doh, M.D. is a resident of Oklahoma and a citizen of the United States. Dr. Doh is a part owner of RMA, and has a financial interest in ProCure OKC.

24. Defendant Gary Larson, M.D. is a resident of Oklahoma and a citizen of the United States. Dr. Larson has a financial interest in RMA and ProCure OKC. Dr. Larson has performed medical director duties at the OKC Facility since 2012. He is also a member of RMI, which is a member of ProCure OKC.

25. Defendant Robert Gaston, M.D. is a resident of Oklahoma and a citizen of the United States. Dr. Gaston's financial interest is evident by virtue of his ownership interest in RMA and as a member of RMI, which is a member and part owner of ProCure OKC.

26. Defendant Kiran Prabhu, M.D. is a resident of Oklahoma and a citizen of the United States. Dr. Prabhu has a financial interest in RMA and ProCure OKC and is also a member of Radiation Oncology Investments, LLC, an Oklahoma limited liability company ("ROI"), which is a member and part owner of ProCure OKC.

27. Defendant Michael Confer, M.D. is a resident of Oklahoma and a citizen of the United States. Dr. Confer has a financial interest in RMA as either a shareholder/owner or investor.

28. Defendant Melisa Boersma, M.D. is a resident of Oklahoma and a citizen of the United States. Dr. Boersma has a financial interest in RMA as either a shareholder/owner or investor.

29. Defendant Elaine Nordhues, M.D. is a resident of Oklahoma and a citizen of the United States. Nordhues has a financial interest in RMA and ProCure OKC. She is a shareholder/owner of RMA and a member of RMI, which is a member and part owner of ProCure OKC.

30. Defendant PCDC is a California corporation with its principal place of business believed to be in Tustin, California. Two (2) physician consultants, who are believed to be residents of California, perform services for ProCure OKC and Parent on behalf of PCDC. PCDC has consulting agreements with both ProCure OKC and Parent which provide annual payments in excess of \$1 Million. On information and belief, PCDC has a separate services arrangement with RMA to aid and/or consult with RMA. The services PCDC provides ProCure OKC under the Consulting Agreement are not to include any direct patient care services or any services RMA is required to provide ProCure OKC under the RMA Agreement.

31. Andrew Chang, M.D. is a resident of California and citizen of the United States. On information and belief, he is an owner in PCDC and, acting as Secretary of PCDC, signed the Consulting Agreement between PCDC and ProCure OKC.

32. Les Yonemoto, M.D. is a resident of California and citizen of the United States. Dr. Yonemoto performs services under the Consulting Agreement and has a financial relationship with PCDC.

IV. FACTS

A. BACKGROUND ON THE APPLICABLE LAWS

Federal Anti-Kickback Statute

33. The Anti-Kickback Statute states that:

(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b).

34. The Anti-Kickback Statute, therefore, makes it illegal to knowingly and willingly solicit or receive any remuneration, or pay any remuneration to induce a referral or recommendation of any item or service that may be paid for under a federal healthcare program.

35. The term “any remuneration” encompasses any kickback, bribe, or rebate, direct or indirect, cover or overt, in cash or in kind.

36. In addition to the criminal penalties associated with violation of the Federal Anti-Kickback Law, the Secretary of the Department of Health and Human Services may impose civil monetary penalties in the amount of up to \$50,000 for each violation, plus damages of up to three (3) times the amount of unlawful remuneration.

37. The Affordable Care Act amended the Anti-Kickback Statute to provide that a person need not have actual knowledge or specific intent to commit an Anti-Kickback violation. See 42 U.S.C. § 1320a-7b(h).

38. The “one purpose rule” has been held to apply to violations of the Anti-Kickback Statute, i.e. even if there are other legitimate reasons for payment, if any *one purpose* is to induce referrals or recommendations for services, there is a violation of the Anti-Kickback Statute.

39. There are regulations that provide safe harbors exempting certain practices and/or arrangements from prosecution and/or sanctions under the Anti-Kickback Statute. However, the requirements to fall within a “safe harbor” must be strictly and precisely met. As will be discussed in more detail below, none of the agreements at issue in this case satisfy the elements of the relevant safe harbor exemption.

Oklahoma Anti-Kickback Statute

40. The Oklahoma Anti-Kickback Statute states that:

Any person who intentionally or knowingly pays to or accepts anything of value from any person, firm, association of persons, partnership or corporation for securing or soliciting patients for any health care professional, health care provider or other entity providing health care services in this state, upon conviction, shall be guilty of a misdemeanor and shall be punished by a fine of not less than Five Hundred Dollars (\$500.00) and not more than Two Thousand Dollars (\$2,000.00).

63 O.S. § 1-742

41. A violation of the Oklahoma Anti-Kickback Statute also carries a punishment involving disciplinary actions by the Oklahoma licensing authority, and allows the licensing authority to bring a separate action to enjoin violations. 63 O.S. § 1-742(A)(2).

42. The Oklahoma Anti-Kickback Statute incorporates the Federal Anti-Kickback Statute safe harbors, holding that payments or arrangements not prohibited by 42 U.S.C. § 1320a-7b(b) are not violations of this statute.

Federal Stark Law

43. The Stark Law states that:

...[I]f a physician (or an immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2), then—

(A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and

(B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).

(2) ...For purposes of this section, a financial relationship of a physician (or an immediate family member of such physician) with an entity specified in this paragraph is—

(A) except as provided in subsections (c) and (d) of this section, an ownership or investment interest in the entity, or

(B) except as provided in subsection (e) of this section, a compensation arrangement (as defined in subsection (h)(1) of this section) between the physician (or an immediate family member of such physician) and the entity.

An ownership or investment interest described in subparagraph (A) may be through equity, debt, or other means and includes an interest in an entity that holds an ownership or investment interest in any entity providing the designated health service.

42 U.S.C. § 1395nn(a).

44. The Stark Law, therefore, makes it illegal for a physician to make a referral for designated health services for which payment may be made under Medicare, Medicaid, or other Federal healthcare program, to an entity with which he/she has a financial relationship.

45. The Stark Law further makes it illegal for an entity to present a claim to Medicare or other Federal healthcare program for designated health services furnished pursuant to a prohibited referral.

46. Radiation therapy services and supplies, the treatment modality ProCure provides, are considered designated health services under Stark. As will be addressed later in this Complaint, there is a radiology oncology exception under the Stark law for referrals meeting specific requirements, but those requirements are not met in the performance of the agreement between PCDC and ProCure OKC or in the actions taken by the PCDC physicians at the OKC Facility.

47. A financial relationship includes indirect and direct compensation arrangements and agreements, and ownership and investment interests.

48. The Stark Law's exceptions identify specific financial relationships that do not violate referral and billing prohibitions, none of which are in existence here.

49. Violators of the Stark Law, which include the entity and physician, are subject to sanctions, including denial of payments, refund of claims, and monetary penalties of up to \$15,000 per claim.

Federal False Claims Act

50. The Federal False Claims Act provides that any person who knowingly submits, or causes the submission of, a false or fraudulent claim to the United States Government for payment or approval is liable for a civil penalty of up to \$11,000 for each claim, and three (3)

times the amount of damages sustained by the Government. Relator brings this action for treble damages and penalties for each false claim submitted.

Oklahoma False Claims Act Violations

51. The Oklahoma Medicaid Program Integrity Act (“OMPIA”) states:

It shall be unlawful for any person to willfully and knowingly:

(6) Solicit or accept a benefit, pecuniary benefit, or kickback in connection with goods or services paid or claimed by a provider to be payable by the Oklahoma Medicaid program.

56 O.S. § 1005(A)(6).

52. The OMPIA incorporates the Federal Anti-Kickback Statute safe harbors, stating that payments or arrangements not prohibited by 42 U.S.C. § 1320a-7b(b) are not violations of this statute.

53. Violators of the OMPIA are liable for a civil penalty of two times the amount of restitution and interest from the date of judgment or a civil penalty of \$2,000 and interest from the date of interest for each false claim. 56 O.S. § 1007(B). Violators can further be criminally liable and be imprisoned for up to three years, and pay a fine of three times the amount of payments illegally obtained. 56 O.S. § 1006(B).

54. The Oklahoma Medicaid False Claims Act (“OMFCA”) states:

Any person who:

1. Knowingly presents, or causes to be presented, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval;

2. Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;

....

is liable to the State of Oklahoma for a civil penalty of not less than Five Thousand Dollars (\$5,000.00) and not more than Ten Thousand Dollars (\$10,000.00), unless a penalty is imposed for the act of that person in violation of this subsection under the Federal False Claims Act for the same or a prior action, plus three times the amount of damages which the state sustains because of the act of that person.

63 O.S. § 5053.1(B).

B. BACKGROUND ON PROCURE

55. ProCure OKC was founded in 2005 and began clinical operations in 2009. It is believed to be the entity which owns the OKC Facility.

56. ProCure's business model involved providing cancer patients with proton therapy, a procedure that represents less than 1% of all radiation therapy provided to cancer patients.

57. The Parent, as reflected in the day-to-day operations and management, controls ProCure OKC and makes all meaningful decisions governing the ProCure OKC and the OKC Facility.

58. In 2012, the Parent brought in a management company, Defendant Loughlin Management, to make ProCure OKC more financially successful, and to take necessary steps to make ProCure OKC attractive to a purchaser. At the direction of the Parent, individual Loughlin Management partners and consultants, including Defendant Knizley and Loughlin, became Board members and/or officers of the Parent and ProCure OKC.

59. Proton therapy is an expensive, alternative cancer treatment costing approximately \$40,000 for a Medicare beneficiary. Due to its expense, and relative lack of long term academic studies regarding comparative outcomes and side effects versus more established treatments, it is a controversial therapy.

60. From the beginning, it was recognized that to obtain patients, ProCure OKC needed "clinical partners" who would refer or induce referral of patients to the OKC Facility. After Loughlin Management became involved with ProCure OKC, the effort to further incentivize and increase the number of "clinical partners" was increased.

C. RMA AND ITS AGREEMENT WITH PROCURE OKC

61. ProCure OKC, through its Parent, first undertook a Professional Services Agreement with RMA as a clinical partner in 2006, at or about the time the OKC Facility opened.

62. This Professional Services Agreement allowed RMA to utilize the OKC Facility. The Professional Services Agreement did not provide any remuneration to RMA physicians.

63. In 2009, in connection with the commencement of services at the OKC Facility, ProCure OKC, at the direction of Parent and Ford, entered into the RMA Agreement with RMA. On information and belief, the RMA Agreement was entered, at least in part, to induce RMA physicians into referring patients to ProCure for proton therapy as opposed to recommending or referring for other treatment modalities.

64. Although not written as such, one purpose of this RMA Agreement was to increase referrals to the OKC Facility. The tacit and underlying purpose or goal of the RMA Agreement was that physician owners or employees of RMA, a large radiology oncology group with physicians practicing in multiple locations, would maintain and boost patient counts and, therefore, increase revenue for ProCure OKC.

65. The compensation under the RMA Agreement is, on information and belief, paid out to all physician owners of RMA, making all of them complicit in entering into this fraudulent agreement.

66. The RMA Agreement pays \$350,000 for RMA to appoint one of its physicians to serve as a part-time medical director at the OKC Facility and perform a "Schedule of Services."

67. This Schedule of Services includes providing assistance in compliance and general clinical supervision, assisting in marketing and developing educational programs,

preparing reports on the operations of the OKC Facility and its quality of care, overseeing scheduling and attempting to grow and develop the OKC Facility.

68. Since 2009, services in the Schedule of Services were minimally provided. To Relator's knowledge, the most time spent by any appointed medical director was at most 10-11 hours per week and usually much less.

69. To Relator's knowledge, very little, if any, verification or record of performance of any services was ever provided nor formally requested by ProCure OKC or the Parent prior to Relator being named President of ProCure OKC. When the Relator requested that records be provided, he was told to "not rock the boat" and that it was "above [his] pay grade" by Board members and senior management of the Parent.

70. Based on lack of documentation of services provided and comments from RMA physicians, OKC Facility staff, and ProCure OKC employees, support the fact that few services were provided.

71. Instead of being paid for services actually performed under the RMA Agreement, RMA and its members received \$350,000 per year primarily to induce its physicians to refer patients to ProCure OKC.

72. RMA, through physician defendants Taylor, Doh, Larson, Gaston, Prabhu, Confer, Boersma, and Nordhues, was the referral source for the vast majority of patients that received proton therapy at the ProCure OKC Facility.

73. Although written to meet the personal services safe harbor provision of the Federal Anti-Kickback Law, the performance of the RMA Agreement did not meet the safe harbor requirements.

74. The personal services and management contracts safe harbor provision states:

As used in section 1128B of the Act, “remuneration” does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as all of the following seven standards are met—

- (1) The agency agreement is set out in writing and signed by the parties.
- (2) The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.
- (3) If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.
- (4) The term of the agreement is for not less than one year.
- (5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.
- (6) The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.
- (7) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

42 U.S.C. § 1001.952(d).

75. On information and belief, the RMA Agreement was not evaluated for commercial reasonableness or fair market value until Relator requested that such an evaluation be done in 2015.

76. The requirements of commercial reasonableness and fair market value were not met, not only due to RMA and ProCure’s six-year failure to have the agreement evaluated for

fair market value, but because RMA was and is being paid for services it did not and does not perform. The real value of the RMA Agreement was and is referrals induced thereby.

77. The Relator asserts that Parent, various executives and Board members, and even compliance personnel were aware that the services under the RMA Agreement were not being performed. They refused to demand performance of the RMA Agreement in accordance with its terms and in order to bring it into compliance with safe harbor requirements, fearing it would cause RMA to stop referring patients to the OKC Facility, thereby costing ProCure OKC large sums of money.

78. Because the RMA Agreement and the performance thereunder do not meet a Federal Anti-Kickback Statute's safe harbor exemption, it also does not meet the Oklahoma Anti-Kickback Statute's exception.

D. PCDC AND ITS CONSULTING AGREEMENT WITH PROCURE

79. Due to RMA's failure to both provide adequate medical director and other services as set out in the RMA Agreement and the need for more referral sources, ProCure looked for another "clinical partner" in 2014 in order to boost revenues.

80. The Parent was convinced that the OKC Facility needed more referrals to survive financially and believed a new clinical partner would bring in those referrals.

81. In 2014, a new agreement is proposed — the PCDC Consulting Agreement ("Consulting Agreement") — by Parent executive Defendant Knizley, acting COO of ProCure Parent and consultant with Loughlin Management, with support from Defendants Loughlin and Loughlin Management. The Consulting Agreement was between ProCure OKC and PCDC, with a second contract in place to increase payments to PCDC to an amount that ProCure OKC alone could not pay. It is believed that Knizley negotiated and executed both contracts in 2014.

82. PCDC was paid jointly by Parent and ProCure OKC, with Parent paying approximately \$250,000 and ProCure OKC paying approximately \$850,000.

83. It was believed that, by virtue of the proton therapy experience of the two (2) physicians associated with PCDC, additional patients would contact the OKC Facility, have appointments with the PCDC physicians, and be referred/recommended by the PCDC physicians for proton therapy at the OKC Facility.

84. One purpose, if not the main purpose, of this Consulting Agreement was to induce increased referrals to the OKC Facility. Although not written as such, the tacit and underlying purpose of the Consulting Agreement was that PCDC's referrals would boost patient counts.

85. Although the Consulting Agreement was written to meet the personal services safe harbor provision of the Federal Anti-Kickback Statute, the performance thereof did not meet safe harbor requirements.

86. As noted above, the Federal Anti-Kickback Statute requires all seven standards to be met for the safe harbor exception to be met. The standards are not met by the terms or performance of the Consulting Agreement.

87. Because the Consulting Agreement does not meet the Federal Anti-Kickback Statute's safe harbors, it does not meet the Oklahoma Anti-Kickback Statute's exceptions.

88. Further, the requirements of the Stark Law safe harbor exception for personal services and management contracts, which have not been met, state:

Remuneration from an entity under an arrangement (including remuneration for specific physicians' services furnished to a nonprofit blood center) if—

(i) the arrangement is set out in writing, signed by the parties, and specifies the services covered by the arrangement,

- (ii) the arrangement covers all of the services to be provided by the physician (or an immediate family member of such physician) to the entity,
- (iii) the aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement,
- (iv) the term of the arrangement is for at least 1 year,
- (v) the compensation to be paid over the term of the arrangement is set in advance, does not exceed fair market value, and except in the case of a physician incentive plan described in subparagraph (B), is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties,
- (vi) the services to be performed under the arrangement do not involve the counseling or promotion or a business arrangement or other activity that violates any State or Federal law, and
- (vii) the arrangement meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

42 U.S.C. § 1395nn(e)(3).

89. It is Relator's opinion that Defendants ProCure and PCDC believed that the written terms of the Consulting Agreement would reflect a commercially reasonable arrangement and, therefore, fit within the exceptions to referral prohibition laws. However, ProCure and PCDC did not expect that PCDC and its physicians would be working the hours required under the agreement, would actually provide all the contracted services, and would accurately document the work done and time involved.

90. As written, the two physicians were to consult (as that term is used in the Consulting Agreement) for ProCure, acting as one physician FTE (full-time equivalent). However, the physicians have provided little, if any, true consulting work, with a significant amount of their time billed at high rates solely for the travel to and from the OKC Facility from California.

91. Despite Relator's efforts to force PCDC to comply with the terms of the Consulting Agreement, documentation continued to be lacking, with such consulting "work" done on a "wink-wink, nod-nod" basis.

92. The entity in control of ProCure OKC, the Parent, was not concerned that PCDC was being paid high amounts for less work than required under its contract, because the Parent's only interest was in measurable revenue results from PCDC, i.e. increased referrals of patients. The Consulting Agreement was undertaken to obtain these referrals, with a limited desire for any actual "consultation".

93. With knowledge that work was not done in accordance with the terms of the Consulting Agreement, the Parent still obtained the true benefit they desired from the contract—more patients and far greater technical revenues.

94. Neither the performance of the terms of the Consulting Agreement nor the actions by the PCDC physicians meet the radiation oncology exception for Stark Law, which states that:

A request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, a request by a radiologist for diagnostic radiology services, and a request by a radiation oncologist for radiation therapy, if such services are furnished by (or under the supervision of) such pathologist, radiologist, or radiation oncologist pursuant to a consultation requested by another physician does not constitute a "referral" by a "referring physician".

42 U.S.C. § 1395nn(h)(5)(C).

95. PCDC physicians Chang and Yonemoto have privileges at only one other facility in Oklahoma City but, on information and belief, have never recommended or referred patients there. They will refer and/or recommend proton therapy at the OKC facility to almost all patients that are seen by them.

96. These referrals by PCDC to the OKC Facility are disguised to fall within the exception to Stark.

97. A majority of PCDC's patients referred to the OKC Facility do not come from an outside consultation. Instead, patients contact the OKC Facility directly. Appointments are made with the PCDC physicians who then refer or recommend the patients for proton therapy at the OKC Facility. These direct-to-consumer patients are primarily for prostate cancer and are beneficiaries under a Federal health insurance program.

98. In a scheme put in place by Loughlin Management, PCDC, RMA, ProCure, and the individual defendants to circumvent the Stark Law, an after-the-fact "request for consult" was directed to the PCDC physicians to fulfill the Stark Law radiation oncology exception.

E. AMOUNT OF CLAIMS PAYABLE UNDER A FEDERAL OR STATE HEALTHCARE PROGRAM

99. On average, ProCure OKC has annual revenues ranging from \$15 - \$25 Million.

100. In 2014, after implementation of the Consulting Agreement to supplement the RMA Agreement, the OKC Facility had a steady stream of 40-60 patients at all times. A vast majority of those patients received proton therapy at the OKC Facility by virtue of a recommendation and/or referral from RMA or PCDC physicians.

101. It is estimated that approximately fifty percent (50%) of ProCure OKC's proton therapy patients were beneficiaries under a Federal or State healthcare program.

102. The average cost for a full round of treatment for a beneficiary of a Federal health insurance plan is \$38,000-\$40,000. However, each course of therapy includes multiple treatments and attendant ancillary services billed and submitted as separate claims. Therefore, each round of treatment generates hundreds of individual claims to federal agencies.

103. Although fifty percent (50%) of ProCure OKC's patients are Medicare/Medicaid or insured under another Federal or state program, it is estimated that patients under such Federal health insurance programs accounted for approximately one-third of ProCure OKC's revenues.

104. Thus, it is estimated that the Parent and ProCure OKC fraudulently claimed and received reimbursement from a Federal or State healthcare program of approximately \$40,000,000 over the course of six (6) years — from 2009 to 2015.

V. COUNT 1- VIOLATIONS OF FEDERAL ANTI-KICKBACK STATUTE (ALL DEFENDANTS)

105. Relator incorporates all the above paragraphs as if fully set out herein.

106. Defendants ProCure OKC, Parent, Ford, and RMA and its members Taylor, Doh, Larson, Gaston, Prabhu, Confer, Boersma, and Nordhues entered into a medical director agreement, the RMA Agreement, that violates the Federal Anti-Kickback Statute because payments to RMA constitute remuneration offered to induce, or in return for, the referral of business paid by federal programs, including Medicare or Medicaid.

107. Defendants ProCure OKC, Parent, and Parent executives including the individual defendants knowingly made payments to RMA as financial inducement for patient referrals and not for services provided under the RMA Agreement. These services provided the referred patients were paid for by Federal or State programs, including Medicare and Medicaid, in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

108. By referring patients to the OKC Facility, in part or in whole because ProCure OKC paid RMA \$350,000 per year, all defendants violated the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

109. The RMA Agreement is not protected under the existing safe harbor regulations.

110. Since 2009, Defendants ProCure OKC and Parent paid in excess of \$2 million to RMA under the RMA Agreement.

111. Defendants ProCure OKC, Parent, Loughlin Management, Loughlin, Knizley, PCDC and its physicians Chang and Yonemoto entered into consulting agreements (the Consulting Agreement) that violate the Federal Anti-Kickback Statute because payments to PCDC constitute remuneration offered to induce, or in return for, the referral of business paid by federal programs, including Medicare or Medicaid.

112. Defendants ProCure OKC, Parent, Loughlin Management, Knizley, and Loughlin knowingly made payments to PCDC and its physicians for services not provided under the Consulting Agreement as financial inducement for patient referrals. These services were paid for by federal programs, including Medicare and Medicaid, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

113. By referring patients to the OKC facility, in part or in whole because ProCure paid PCDC large sums under the Consulting Agreement, defendants violated the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).

114. The services which were performed under the Consulting Agreement or otherwise by the PCDC physicians are not protected under the existing safe harbor regulations.

115. Defendants ProCure OKC and Parent have paid in excess of \$1.1 million to PCDC.

116. For each of these Federal Anti-Kickback Statute violations, Defendants are subject to penalties of up to \$50,000 for each improper act, plus damages of up to three times the amount of improper remuneration at issue. 42 U.S.C. § 1320a-7a(a).

WHEREFORE, Relator requests the following:

- a) Judgment against the Defendants in an amount equal to and up to three times the amount of the improper remuneration at issue;
- b) Penalties up to \$50,000 for each anti-kickback violation;
- c) Attorneys' fees and costs; and
- d) Any other relief, at law or in equity, the Court deems just.

VI. COUNT 2- VIOLATIONS OF FEDERAL STARK LAW (PCDC, CHANG, YONEMOTO, PARENT, KNIZLEY, LOUGHLIN MANAGEMENT, LOUGHLIN, AND PROCURE OKC)

117. Relator incorporates all the above paragraphs as if fully set out herein.

118. PCDC and its physicians Chang and Yonemoto had a financial relationship with Defendants ProCure OKC and Parent to which the Stark Law applies, namely the remuneration ProCure OKC and Parent paid under the Consulting Agreement.

119. PCDC, by and through its physicians Chang and Yonemoto, referred Medicare and Medicaid patients for designated health services to the ProCure OKC facility, an entity with which it had a financial relationship, in violation of the Stark Law, 42 U.S.C. § 1395nn.

120. None of the Stark Law exceptions apply to the financial relationship or illegal referrals between PCDC and Defendants ProCure OKC and Parent.

121. Each referral by a PCDC physician to ProCure OKC's OKC Facility of a Medicare or Medicaid patient for designated health services constituted a violation of the Stark Law, 42 U.S.C. § 1395nn.

122. Claims submitted by ProCure OKC for Medicare and Medicaid reimbursement related to these fraudulent referrals constitute violations of the Stark Law, 42 U.S.C. § 1395nn.

123. Each referral of a Medicare patient for proton therapy, a designated health service, by a physician member of PCDC to the OKC Facility constituted a violation of the Stark Law.

WHEREFORE, Relator requests the following:

- a) Judgment against the Defendants in an amount equal to a refund of all Medicare and Medicaid claims paid for the designated health services that resulted from an illegal referral;
- b) Sanctions against Defendants, including, without limitation, denials of payments and refunds of claims;
- c) Penalties up to \$15,000 for each Stark Law violation;
- d) Attorneys' fees and costs; and
- e) Any other relief, at law or in equity, the Court deems just.

VII. COUNT 3- VIOLATION OF FEDERAL FALSE CLAIMS ACT (ALL DEFENDANTS)

124. Relator incorporates all the above paragraphs as if fully set out herein.

125. Defendants ProCure OKC, Parent, Knizley, Ford, Loughlin Management, and Loughlin provided incentives accepted by RMA, PCDC, and their members Taylor, Doh, Larson, Gaston, Prabhu, Confer, Boersma, Nordhues, Chang, and Yonemoto to induce fraudulent referrals for services to the OKC Facility for the provision of health services to beneficiaries under a Federal health insurance plan in violation of the Federal Anti-Kickback Statute.

126. Defendants' violations of the Federal Anti-Kickback Statute give rise to liability under the Federal False Claims Act.

127. As a requirement to participating in federal health insurance programs, all Defendants confirmed their compliance with the Federal Anti-Kickback Statute.

128. Defendants violated the Federal False Claims Act by submitting claims or having claims substituted on their behalf for reimbursement from federal health insurance programs, knowing they were ineligible for payments due to the Anti-Kickback Statute violations.

129. Each claim submitted by Defendants to a federal health insurance program for a service provided to a patient referred by RMA, PCDC, or their respective members Taylor, Doh, Larson, Gaston, Prabhu, Confer, Boersma, Nordhues, Chang, and Yonemoto to the OKC Facility is a false claim due to the referrals obtained through fraudulent kickbacks.

130. Further, Defendant PCDC and its physicians, as alleged above, had a financial relationship with ProCure OKC and Parent, and referred Medicare and Medicaid patients for proton therapy to ProCure OKC and Parent's facility in violation of the Stark Law.

131. Claims submitted by ProCure OKC to the government for reimbursement related to these fraudulent referrals are also violations of the Stark Law.

132. Defendants knowingly caused to be made or used false records or statements, such as the false representation of compliance with the Anti-Kickback and Stark laws, when claims were submitted and paid and/or approved in violation of the False Claims Act, 31 U.S.C. § 3729(a)(3).

133. All of Defendants' actions as alleged in this Complaint were knowing, as that term is used in the Federal False Claims Act.

WHEREFORE, Relator requests the following:

- a) Judgment against the Defendants for three times the amount of damages the United States has sustained because of their actions, plus a civil penalty of \$11,000 for each violation of the Federal False Claims Act;
- b) 25% of the proceeds of this action if the United States elects to intervene, and 30% if it does not;
- c) Attorneys' fees and costs; and
- d) Any other relief, at law or in equity, the Court deems just.

VIII. COUNT 4- VIOLATION OF THE OKLAHOMA ANTI-KICKBACK STATUTE (ALL DEFENDANTS)

134. Relator incorporates the above paragraphs as if fully set out herein.

135. Defendants ProCure OKC, Parent, Knizley, Ford, Loughlin Management, and Loughlin provided incentives to RMA and PCDC to secure and/or solicit patients for health services.

136. Defendants ProCure OKC, Parent, Knizley, Ford, Loughlin Management, and Loughlin knowingly, as it is defined herein, made excessive payments to RMA, PCDC, and the physicians associated therewith, as financial inducement for patient referrals to the OKC Facility.

137. Defendants RMA, PCDC, and their members Taylor, Doh, Larson, Gaston, Prabhu, Confer, Boersma, Nordhues, Chang, and Yonemoto knowingly, as it is defined herein, accepted excessive payments from ProCure OKC and Parent for inducement to provide referrals to the OKC Facility.

138. Because none of the Federal Anti-Kickback Statute safe harbor exceptions apply, there is no exception under the Oklahoma Anti-Kickback Statute.

139. For each of these Oklahoma Anti-Kickback Statute violations, Defendants are liable for a fine between \$500 to \$2,000 dollars.

WHEREFORE, Relator requests the following:

- a) Judgment against the Defendants for a fine of not less than \$500 and not more than \$2,000 for each violation;
- b) Attorneys' fees and costs; and
- c) Any other relief, at law or in equity, the Court deems just.

IX. COUNT 5- VIOLATIONS OF THE OMPIA AND OMFCA (OKLAHOMA MEDICAID PROGRAM INTEGRITY ACT AND FALSE CLAIMS ACT) (ALL DEFENDANTS)

140. Relator incorporates the above paragraphs as if fully set out herein.

141. Defendants ProCure OKC, Parent, Knizley, Ford, Loughlin Management, and Loughlin knowingly, as it is defined herein, made excessive payments to RMA and PCDC, which RMA, PCDC, and their members Taylor, Doh, Larson, Gaston, Prabhu, Confer, Boersma, Nordhues, Chang, and Yonemoto accepted as financial inducement for patients that are beneficiaries under the Oklahoma Medicaid Program.

142. Because Defendants do not meet any of the safe harbor exceptions under the Federal Anti-Kickback Statute or Oklahoma Anti-Kickback Statute, they do not meet the OMPIA false claims exception under 56 O.S. § 1005(C).

143. Each claim submitted by Defendants to the Oklahoma Medicaid program for a service provided to a patient referred by RMA or PCDC physicians to the OKC Facility is a false claim due to the fact that the referrals were obtained through fraudulent kickbacks.

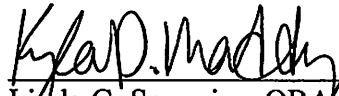
WHEREFORE, Relator requests the following:

a) Judgment against the Defendants for three (3) times the amount of damages the United States has sustained because of their actions, plus a civil penalty of up to \$10,000 for the violation of the OMFCA, and a civil penalty of two times the amount of restitution and interest from the date of judgment for each false claim in violation of the OMPIA;

b) Attorneys' fees and costs; and

c) Any other relief, at law or in equity, the Court deems just.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "Kaylee P. Davis-Maddy", is written over a horizontal line.

Linda G. Scoggins, OBA #8013

Kaylee P. Davis-Maddy, OBA #31534

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